Claims

1. A subcutaneous implantable cardioverter-defibrillator comprising:

(A) an electrically active canister that serves as either an anode or a cathode of the cardioverter-defibrillator wherein the canister houses a source of electrical energy, a capacitor, and operational circuitry that senses the presence of potentially fatal heart rhythms;

(B) a subcutaneous electrode that serves as the opposite electrode from the canister (either the anode or the cathode);

(C) a lead system electrically attaching the electrode to the canister;

(D) means for delivering electrical cardioversion-defibrillation energy when the operational circuitry senses a potentially fatal heart rhythm; and

(E) the absence of a transvenous, intracardic, or epicardial electrode.

2. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is equal to or greater than 800 Volts.

3. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy ranges from about 40 Joules to about 150 Joules.

4. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the subcutaneous electrode is a composite electrode comprising:

(A) a cardioversion-defibrillation electrode;

(B) a first sensing electrode; and

(C) a second sensing electrode electrically insulated and spaced apart from the first sensing electrode.

5. The subcutaneous implantable cardioverter-defibrillator of Claim 4 wherein the first sensing electrode is located at the distal end of the subcutaneous electrode, the second sensing electrode is located about 1 to about 10 cm proximal to the first sensing electrode, and the cardioversion-defibrillation electrode is located proximal to the second sensing electrode.

6. The subcutaneous implantable cardioverter-defibrillator of Claim 5 wherein the first and second sensing electrodes are spaced apart by about 4 cm.

7. The subcutaneous implantable cardioverter-defibrillator of Claim 4 wherein the first sensing electrode is located at the distal end of the subcutaneous electrode, the cardioversion-defibrillation electrode is located proximal to the first sensing electrode, and the second sensing electrode is located proximal to the cardioversion-defibrillation sensing electrode.

8. The subcutaneous implantable cardioverter-defibrillator of Claim 4 wherein the cardioversion-defibrillation electrode is located at the distal end of the subcutaneous electrode, the first sensing electrode is located proximally to the carioversion-

defibrillation electrode, and the second sensing electrode is located about 1 to about 10 cm proximal to the first sensing electrode.

9. The subcutaneous implantable cardioverter-defibrillator of Claim 8 wherein the first and second sensing electrodes are spaced apart by about 4 cm.

10. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can also sense the presence of bradycardia rhythm.

11. The subcutaneous implantable cardioverter-defibrillator of Claim 10 further comprising means for delivering cardiac pacing energy when the operational circuitry senses a bradycardia rhythm.

12. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry is programmable.

13. The subcutaneous implantable cardioverter-defibrillator of Claim1 wherein the operational circuitry can detect tachycardia.

14. The subcutaneous implantable cardioverter-defibrillator of Claim 13 further comprising means for delivering antitachycardia pacing when the operational circuitry senses a tachycardia rhythm.

15. The subcutaneous implantable cardioverter-defibrillator of Claim 13, wherein the ventricular tachycardia detected is greater than 240 beats per minute.

16. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can detect atrial tachycardia and atrail fibrillation.

17. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry can induce ventricular tachycardia or ventricular fibrillation.

18. The subcutaneouos implantable cardioverter-defibrillator of Claim 17 wherein the ventricular tachycardia or ventricular fibrillation is induced by shocks on the T wave.

19. The subcutaneous implantable cardioverter-defibrillator of Claim 17 wherein the ventricular tachycardia or ventricular fibrillation is induced by low direct current voltage applied during the entire cardiac cycle.

20. The subcutaneous implantable cardioverter-defibrillator of Claim 2 wherein the electrical cardioversion-defibrillating energy ranges from about 800 volts to about 2000 volts.

21. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is delivered in a biphasic waveform.

22. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the capacitance is about 50 to about 200 microfarads.

23. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is malleable.

24. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is provided with at least one sensing electrode.

25. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is provided with one or more sensing electrodes, the subcutaneous electrode is provided with one or more sensing electrodes, and means for selecting two sensing electrodes from the sensing electrodes located on the canister and the sensing electrode located on the subcutaneous electrode that provide adequate QRS wave detection.

26. The subcutaneous implantable cardioverter-defibrillator of Claim 1 comprising an additional subcutaneous electrode that serves as the opposite electrode from the canister (either the anode or the cathode) and the same polarity as the original subcutaneous electrode.

27. The subcutaneous implantable cardioverter-defibrillator of Claim 1 comprising an additional subcutaneous electrode that serves as the opposite electrode

from the original subcutaneous electrode (either the anode or the cathode) and the same polarity as the canister.

28. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the electrical cardioversion-defibrillating energy is delivered for about 10 to about 20 milliseconds total duration and with the initial positive phase containing approximately 2/3 of the energy delivered.

29 The subcutaneous implantable cardioverter-defibrillator of Claim 1 further comprising an attachment member located at the distal end of the subcutaneous electrode for attaching the subcutaneous electrode to nearby tissue.

30. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the operational circuitry comprises an impedance detection for measuring the undulations in transthoracic impedance created during respiration.

31. The subcutaneous implantable cardioverter-defibrillator of Claim 30 wherein the operational circuitry can also measure the cardiac output using transthoracic impedence.

32. The subcutaneous implantable cardioverter-defibrillator of Claim 16 wherein the operational circuitry can deliver defibrillation energy to treat the detected atrial fibrillation.

33. The subcutaneous implantable cardioverter-defibrillator of Claim 1 wherein the canister is long, thin, and curved such that it is shaped to be subcutaneously implanted adjacent to and parallel with ribs of a patient.

34. A method of implanting a subcutaneous cardioverter-defibrillator in a patient comprising the steps of;

(1) making only one skin incision in the thoracic region of the patient;

(2) inserting a curved introducer through the skin incision to make a subcutaneous path in the thoracic region such that the path terminates subcutaneously at a location that if a straight line were drawn from the skin incision to the path termination the line would intersect the heart of the patient;

(3) implanting an electrode subcutaneously at the path termination point;

(4) placing an electrically active canister subcutaneously at the skin incision point wherein the canister contains a source of electrical energy and operational circuitry that senses the presence of potentially fatal heart rhythms and has means for delivering electrical cardioversion-defibrillation energy using the canister as either the anode or the cathode and using the electrode as the opposite electrode from the canister, and wherein the canister is electrically connected to the electrode; and

(5) closing the skin incision.

35. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 further comprising the step of injecting a local anesthetic through the curved introducer.

36. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 wherein the skin incision is located in the left anterior axillary line approximately at the level of the patient's cardiac apex.

37. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 36 wherein the electrode is subcutaneously implanted in the left posterior axillary line lateral to the left scapula.

38.The method of implanting a subcutaneous cardioverter-defibrillator of Claim 36 wherein the canister is subcutaneously implanted in the left inframammary crease of the patient.

39. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 wherein the skin incision is located in the left posterior axillary line of the patient approximately at a level lateral to the tip of the left scapula of the patient.

40. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 39 wherein the electrode is implanted in the anterior pericardial region of the patient.

41. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 40 wherein the electrode is implanted in the inframammary crease of the patient.

42. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 34 wherein the operational circuitry can detect the presence of bradycardia rhythms.

43. The method of implanting a subcutaneous cardioverter-defibrillator of Claim 42 wherein the device has means of delivering electrical cardiac pacing energy when the operational circuitry senses a bradycardia rhythm.

44. A subcutaneous implantable cardioverter-defibrillator kit comprising:

(A) a tray for storing the subcutaneous implantable cardioverter-defibrillator;

(B) an electrically active canister that serves as either an anode or a cathode of the cardioverter-defibrillator wherein the canister houses a source of electrical energy and operational circuitry that senses the presence of potentially fatal heart rhythms stored in the tray;

(C) an electrode that serves as the opposite electrode from the canister (either the anode or the cathode) stored in the tray;

(D) a lead system electrically attaching the electrode to the canister stored in the tray; and

(E) means for delivering electrical cardioversion-defibrillation energy when the operational circuitry senses a potentially fatal heart rhythm stored in the tray.

45. The subcutaneous implantable cardioverter-defibrillator kit of Claim 44 further comprising a curved introducer stored in the tray.

46.The subcutaneous implantable cardioverter-defibrillator kit of Claim 45 further comprising a local anesthetic for injecting through the curved introducer stored in the tray.

47. The subcutaneous implantable cardioverter-defibrillator kit of Claim 45 further comprising a curved rigid peel away sheath stored in the kit.